

# **ACT-Accelerator Vaccine Pillar (COVAX) Civil Society & Community Representation**

## *Notes to assist in nomination of representatives*

This document is intended to offer guidance to civil society and community-led organizations to nominate their representatives for consideration to participate in the COVAX Coordination Meeting (CCM) and specific workstreams of the ACT-Accelerator vaccines pillar.

Nominations should be submitted by email to [CSO\\_COVAX@who.int](mailto:CSO_COVAX@who.int) with CVs and a brief covering note, clearly indicating whether the nomination is for the CCM or a specific workstream. Please note that 3-4 nominations may be submitted for the 1 representative position on the CCM, and in addition 3-4 nominations may be submitted for each of the groups/sub-groups. It is not possible to nominate the same individual for the CCM and the sub-groups.

**Deadline: 14 September 2020**

Note that representation of civil society organizations and communities on the COVAX pillar is additional to engagements and dialogues through other mechanisms for the wider community, e.g. regular webinars, updates and interactions through the Gavi CSO constituency, etc.

### **Background on engagement of civil society and community representatives**

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Civil society and community organisations have an important role to play in the development and implementation of the COVAX pillar as well as deployment of any successful vaccine coming out of COVAX, e.g. in building political will for immunization, building capacity and capability as well as public trust for vaccination with future COVID-19 vaccines.

The civil society and community representatives advocate the viewpoints and needs of NGOs and communities within the ACT-Accelerator Vaccines pillar supported by a lead facilitative organization. They also engage with community and civil society representatives as identified in other pillars/cross-cutting platforms/connectors or elements of the ACT-A partnership and help build a constituency of NGOs and community organisations.

### **ACT-Accelerator (ACT-A) and the vaccines pillar (COVAX)**

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The ACT-Accelerator (ACT-A) is designed to accelerate the development, production and equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines.

Developing a vaccine against COVID-19 is one of the most pressing and complex challenge of our time. The global pandemic has already caused the loss of hundreds of thousands of lives and disrupted the lives of billions more. Many leaders have called for a global solution to address a global issue and for a shared endeavor that involves the best shared science to resolve in the shortest possible time a pandemic involving every region and territory on the planet. The COVAX Pillar provides this solution. The goal of the COVAX Pillar is to end the acute phase of the global pandemic by the end of 2021. Read more [here](#).

Figure 1 (below): Depiction of the ACT Accelerator and the three pillars (vaccines, therapeutics and diagnostics), as well as the cross-cutting health systems connector.

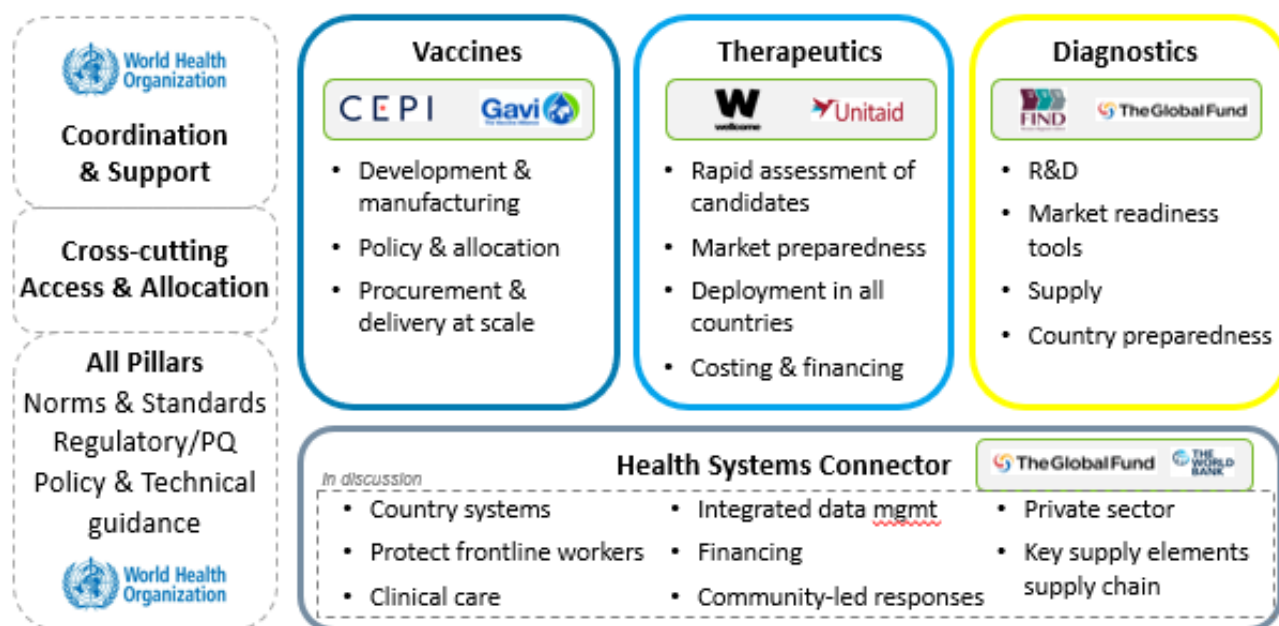


Figure 2 (below): Proposed CSO representation in workstreams shown in green, in addition to the CCM, which cross-cuts the three areas below. In addition to this representation, added mechanisms are being established to routinely update, engage and receive input from the CSO community across all workstreams.

COVAX Coordination Meeting (CCM)	<b>Development &amp; manufacturing</b> Led by CEPI, with industry	Active portfolio management and supporting activities including: enabling science, manufacturing, clinical development and operations	<ul style="list-style-type: none"> <li>• <b>Technical Review Group (TRG)</b></li> <li>• <b>Enabling science – sub-team (SWAT)</b></li> <li>• <b>Manufacturing – sub-team (SWAT)</b></li> <li>• <b>Clinical development and operations – sub-team (SWAT)</b></li> </ul>
	<b>Policy &amp; allocation</b> Led by WHO	Vaccine strategy and policy, access and allocation, ethical guidelines	<ul style="list-style-type: none"> <li>• <b>Vaccine strategy</b></li> <li>• <b>Access and allocation</b></li> <li>• CSOs are already part of SAGE:                         <ul style="list-style-type: none"> <li>- Dr Folake Olayinka (JSI) – SAGE member</li> <li>- Dr Chizoba Wonodi (Gavi CSO Board)</li> </ul> </li> </ul>
	<b>Procurement &amp; delivery at scale</b> Led by Gavi	Procurement (incl. COVAX Facility, AMC), country readiness and delivery, monitoring and learning	<ul style="list-style-type: none"> <li>• <b>Country Readiness and Delivery coordination group</b></li> <li>• <b>Country Readiness and Delivery – demand sub-group</b></li> <li>• <b>Country Readiness and Delivery – communication, advocacy and training sub-group</b></li> </ul> CSO reps already in following groups + Gavi CSO Steering Committee: <ul style="list-style-type: none"> <li>• 1 CSO rep already on Gavi Board</li> <li>• 1 CSO rep already in the Market Sensitive Decisions Committee</li> <li>• 1 CSO rep already in the Programme and Policy Committee</li> <li>• 3 CSO interim reps already in COVAX HSS-Connector data working group</li> <li>• 1 CSO rep already in Gavi's Evaluation Advisory Committee</li> </ul>

## Nominations are sought for the following sub-groups (in addition to the CCM):

- Technical review group (TRG)
- Development and manufacturing sub-teams (SWAT teams):
  - Enabling science
  - Manufacturing
  - Clinical development and operations
- Vaccine strategy
- Access and allocation
- Country Readiness and Delivery Coordination Group
- Country Readiness and Delivery – demand sub-group
- Country Readiness and Delivery – communications, advocacy and training sub-group

## General notes to guide CSOs in nomination of COVAX representatives in all groups

### General considerations:

- The individual should be committed (as an individual and on behalf of their organization) to the COVAX pillar objectives and deliverables
- Sufficient time should be allocated to attend and make meaningful contributions to meetings
- The appointment will be considered in a person's individual capacity (i.e. cannot be transferred to another person in the same organisation)
- The candidate should be sufficiently expert in their field and well-networked to provide meaningful guidance and contributions to the COVAX Pillar mission
- Ability to work in the English language

### It is envisaged that the civil society representative will:

- **Maintain strict confidentiality** of any oral and written information that is exchanged in relation to the CCM and not disclose any confidential information to third parties
- Familiarize themselves with the objectives, working arrangements and needs of the COVAX Pillar
- Contribute an **independent and impartial** view to discussions based on their experience and their knowledge of the needs and perspectives of communities and civil society, and in considering the coordination processes and systems to enable successful implementation of the COVAX Pillar
- **Bring their experience and acumen** to bear on critical decision making and strategy formulation
- **Act as an advocate** for community and CSO perspectives as appropriate, and within the context of the COVAX Pillar objectives and timing
- **Participate in meetings and teleconferences.**
- **Liaise with the broader constituency** on key issues, except for topics subject to confidentiality requirements
- Follow up on key issues relating to the workstream between meetings, with support from the constituency

## **1. Nominations for the CCM**

The primary objectives of the CCM are as follows:

- Ensure alignment between partners and the wider ACT Accelerator
- Inform and guide major workstream decisions
- Discuss overarching strategic questions
- Overcome bottlenecks as needed, including through high-level stakeholder management
- Take ownership of progress towards agreed goals

Discussions take place through weekly 1-2 hour teleconferences.

### **Particular notes to guide CSOs in nomination of representatives to CCM**

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In addition to the general considerations outlined above, the CCM representative should:

- Be a recognised leader and sufficiently expert and well-networked to provide meaningful guidance and contributions to the COVAX Pillar mission, e.g. through political and community engagement to foster the support necessary to secure equitable access and/or delivery of future COVID-19 vaccines
- Hold a senior role within a globally-recognised CSO with broad capabilities in relation to the pandemic response
- Have a sound understanding of access to immunization and essential services in humanitarian contexts, hard to reach areas, and fragile or conflict-affected territories (considered a strong advantage)

In addition to the above, it is envisaged that the civil society representative to CCM will:

- **Provide in-depth subject-matter expertise** in one or more of the following and related areas: vaccine R&D; manufacturing; delivery; demand; access and allocation; policy; governance
- **Bring their seniority, experience and acumen** to bear on critical decision making, strategy formulation and tactical approaches
- **Act as an advocate** for civil society and community perspectives as appropriate, and within the context of the COVAX Pillar objectives and timelines

## **2. Nominations for workstreams**

The points below for each group/sub-group are intended to offer an outline of the scope and objectives of each group, to guide nomination of CSO representations with appropriate corresponding skills and experience.

### **Technical review group (TRG)**

- Provide end-to-end oversight of SWAT team execution: review and monitor SWAT teams progress and milestones
- Approve SWAT team creation, deliverables and timelines
- Provide technical support and guidance to SWAT teams
- Ensure optimal integration between the work of SWATs and vaccine teams (e.g. managing conflicts of interest, not sharing developer-specific information)
- Discussions take place through weekly 1-hour teleconferences

## **SWATs**

The primary objectives of the three COVAX Research, Development and Manufacturing SWATs are as follows:

- Focus on resolving common technical cross-project questions and challenges
- Act as an open source of information for Vaccine Teams and more widely
- Promote harmonization and comparability across projects
- Bring together different stakeholders and coordinate with other players in the ecosystem to maximize efforts (e.g. ACTIV)

The following key activities are in focus for each of the SWATs:

### **Enabling science SWAT**

- Centralized testing capacity for uniform performance
- Define the type and required performance of diagnostic assays
- Establishment of animal testing network
- Regulatory agreement on appropriate animal models
- Regulatory guidance on vaccine-mediated enhanced disease (VMED)
- Guidance on Correlates of Protection (CoP)
- Discussions take place through monthly 2-3 hour teleconferences on specific topics

### **Manufacturing SWAT**

- Drug product strategy
- Drug product capacity matching
- Drug substance strategy
- Drug substance capacity matching
- Manufacturing requirements for emergency use
- Cost of goods
- Supply chain strategy
- Authority central lab capacity mapped
- Potency assay requirements
- Discussions take place through monthly 2-3 hour teleconferences on specific topics

### **Clinical development and operations SWAT**

- Trial site readiness
- Landscape analysis
- Clinical Trial Application open access database / repository
- Clinical trial (CT) site network set-up
- Workshop on CT site networks
- Adverse Event of Special Interest (AESI) case definitions
- Strategic doc and case definition on vaccine-mediated enhanced disease (VMED)
- Strategic doc on post roll-out vaccine safety surveillance
- Standard CT elements
- Strategy doc Adaptive trial design
- Strategy doc on Correlates of Protection (CoP)
- Strategic docs on alternative/supportive evidence
- Discuss optimization options
- Discussions take place through monthly 2-3 hour teleconferences on specific topics

## **Vaccine strategy**

The Vaccine Strategy sub-workstream has the two-fold task of (i) assuring that the COVAX Pillar has an aligned global COVID-19 vaccine strategy which includes detail on the goals of a vaccination program and general targets for achieving the goals (ii) addressing COVAX-wide strategic topics such as risks to the vaccination strategy, and core scenarios to feed planning and delivery efforts.

The workstream is highly agile to the needs of the other workstreams in COVAX, so additional scope is added as needed.

The current work on overall vaccine strategy, risk assessment, and on core scenarios has been completed. As additional 'sprints' are developed, the nominated CSO representative will be invited as a formal member.

## **Access and allocation**

It is expected that availability of safe and efficacious COVID health technologies will be in short supply till manufacturing capacity incrementally increases to cover all vulnerable groups and all population. A global, fair allocation is needed to promote equitable and affordable access to all COVID-19 health products and to avoid the inequities observed in past pandemics.

A draft fair allocation framework/mechanism has been developed in consultation with Member States, and it is in an advanced stage, with an initial focus on vaccines. The vaccine allocation mechanism will work in close collaboration with the COVAX Facility.

Work on the fair allocation of therapeutics has started under the therapeutics pillar; similar work in the diagnostics pillar has yet to be developed.

The nominated CSO representative will participate as a formal member of the allocation working group.

## **Country readiness and delivery (CRD) coordination group**

- Define, resource and implement overall workplan to ensure country readiness for introduction of a COVAX
- Coordinate progress, engage and communicate with relevant stakeholders
- Anticipate, plan and drive the execution of a range of issues related to country readiness for immunisation delivery (e.g. vaccine programme planning, vaccine demand, vaccine impact monitoring, supply and logistics).
- Discussions take place through weekly 1.5-hour teleconferences.

## **Country readiness and delivery – demand sub-group**

- Support countries to build public acceptance, demand and trust for COVID-19 vaccines
- Leverage COVID-19 vaccine demand activities to enhance uptake of vaccines in general
- Facilitate rapid exchange of tools, approaches and learnings among partners globally
- Connect appropriate technical support to regions and countries by leveraging partner networks and rapidly building the community of practice
- Track progress on key planning and implementation indicators across countries
- Support countries and regions to build on existing coordinating groups in immunization for demand, communications, social listening, risk communications and community engagement
- Build on existing global and regional platforms, e.g. Demand Hub, to leverage similar activities
- Discussions take place through weekly 1-hour teleconferences

## **Country readiness and delivery – communications, advocacy and training sub-group**

The communications, advocacy and training group supports the technical working groups and other partners to create cohesive packages of communications, advocacy and training materials for Member States and other stakeholders to support their preparedness with introduction of COVID-19 vaccines. Core objectives:

- Design and execute global communication/advocacy materials that present COVID-19 country readiness and delivery related technical guidance in direct and easily digestible content and messaging (i.e. videos, posters, talking points, etc.) to reach the intended audience
- Design adaptable training materials (in collaboration with the technical working groups) that may be delivered via a variety of mechanisms, both online and in-person
- Disseminate trainings through existing platforms to reach Member States
- Manage a public-facing web site for the CRD workstream to make available up-to-date materials and guidance for programmes and partners

Discussions take place through weekly 1-hour teleconferences.

## **Particular notes to guide CSOs in nomination of representatives to workstreams**

For the three SWATs and TRG, the following points are put forward for consideration, to guide nominations:

- Knowledge of infectious diseases and transmission
- Experience with public health measures in low- and middle-income country settings
- Scientific background preferred
- Experience with drug development, regulatory affairs, clinical research and/or manufacturing (vaccine development preferred)
- Experience with distribution and deployment of vaccines in low- and middle-income countries
- Experience with distribution and deployment of vaccines in fragile or conflict-affected contexts or emergency settings

For all other groups as listed above, technical expertise should be aligned with the scope and objectives of each group.

## **Candidate selection, duration of term and compensation**

The Civil Society and Communities Representatives will be selected through the following process:

- This call for expressions of interest will be circulated widely through civil society and community mailing lists, as well as posted on social media and other channels
- A selection panel of COVAX pillar representatives will assess applications against the main criteria listed above, aiming to have representation across the required areas of expertise, and to the extent possible ensuring geographical diversity and gender equitable membership
- The selection panel will select the Civil Society and Communities Representatives following this vetting process. The panel will try to reach their decision by consensus
- One CSO representative will be nominated for the CCM and to each of the workstreams
- To the extent possible, nominations should match interests flagged in the application

- If no nominations are achieved for a given workstream, applications for other workstreams may be assessed to seek suitable candidate profiles
- If no applications are received for a given workstream and no suitable profiles are identified through the process, no nominations will be issued

The term of office for the Civil Society & Communities Representative is expected to be approximately 12 months with the possibility of extension through the end of 2021 (with a review expected beginning in April 2021 to determine the likely “end date” of the working groups, workstreams and pillar). Should the work be expected to carry on into 2022 a selection process will be initiated in July 2021 for new representatives to start in September 2021. Representatives will be allowed to re-apply.

### **Cessation of appointment**

The appointment of the Civil Society & Communities Representative will cease if:

- They resign in writing
- They no longer have a contractual link to an NGO or community-based organisation(s)
- If a conflict of interest is declared and it is not possible to work around this
- When their term is completed
- They breach the terms of any Non-Disclosure Agreement entered into by them in relation to their role and activities on the CCM or any of its committees.

### **Compensation**

CSO-representatives in COVAX are not compensated, but travel and other reasonable expenses connected with their service are paid.